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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,151	03/21/2001	Gina Lynn Nick	01/700	2473

7590 10/07/2002
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Laguna Hills, CA 92654

EXAMINER

GITOMER, RALPH J

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/07/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/814,151

Applicant(s)

Nick

Examiner

Ralph Gitomer

Art Unit

1627



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 25, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

The amendment received 6/25/02 has been entered and claims 1-20 are currently pending in this application. It is noted that the amendment was 12 pages total.

5 The rejection of record under 35 U.S.C. 112, first paragraph over claims 17-20, is maintained.

Applicant's arguments filed 6/25/02 have been fully considered but they are not persuasive.

10 Applicant argues that the OASP represents or simulates or mimics the GI tract.

It is the examiner's position that the basis of the rejection is the specification does not teach one of skill in this art how to make and use the invention as claimed. The claims are directed to an in vitro model as an essential feature. 15 What the intended use of the invention may be is irrelevant to the rejection at hand.

20 The rejections of claims 1-16 under 35 U.S.C. 103(a) over the combination of Yu in view of McLachlan and Kelleher are maintained.

Applicant's arguments filed 6/25/02 have been fully considered but they are not persuasive.

25 Applicant argues that there is no motivation to combine the references. The present invention adds H2DCFDA to cells without an antioxidant sample to tag the oxidative species present in the

medium. Then the population of tagged oxygen radicals is measured with a fiber sensor. Yu measures total antioxidant activity of a mixture containing an antioxidant but does not identify the intracellular antioxidant activity of specific antioxidant fortified cells. An optical fiber sensor has advantages over a spectrofluometer. Kelleher is not directed to the same promoter of the present invention, peroxide, to generate excess ROS before adding the antioxidant sample.

It is the examiner's position that both Yu and the present invention employ a spectrophotometer, the difference is the present invention employs fiber optics with the spectrophotometer. McLachlan was cited to show a fiber optic probe for the same function as presently claimed. Employing a known method of detecting with the expected results would have been obvious. No functions are claimed. Regarding the distinction between adding the dye prior to adding the antioxidant as presently claimed, Helleher was cited to show the same. The present claims are not directed to identifying the intracellular antioxidant activity of specific antioxidant fortified cells. No distinction is seen between the present invention's peroxide and the promoters of Kelleher which have the same function.

Furthermore, the 35 USC § 103 statute does not require that the prior art identically disclose or describe Applicant's invention but rather that no patent should be obtained if the

subject matter as a whole would have been obvious to persons having ordinary skill in this art at the time this invention was made.

5 Claims 1-16 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

10 In claim 1 next to last line, ~~the~~said oxygen radical population measurements~~the~~ lacks definite antecedent basis. In claim 16 ~~the~~Trolox~~the~~ appears to be a trademarked name.

15 Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

20 A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire

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on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at www.uspto.gov and click on the button Patent Electronic Business Center for more information.

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